

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

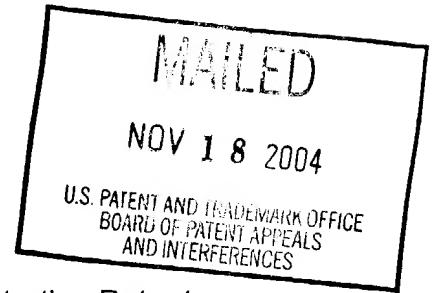
## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BARBARA RONIKER, RICHARD J. LACHAPELLE,  
DANIEL T. CONNOLLY, KAREN SEIBERT, and PHILIP NEEDLEMAN

Appeal No. 2004-1933  
Application No. 09/402,634

ON BRIEF



Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent  
Judges.

ADAMS, Administrative Patent Judge.

#### REMAND TO THE EXAMINER

Our consideration of the record leads us to conclude that this case is not in condition for a decision on appeal. For the reasons that follow, we vacate<sup>1</sup> the pending rejection under 35 U.S.C. § 103 and remand the application to the examiner to consider the following issues and to take appropriate action.

Claim 13 is illustrative of the subject matter on appeal and is reproduced below:

13. A method for the prophylactic treatment of a subject at risk of developing a cardiovascular disorder, selected from coronary artery

<sup>1</sup> Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

disease, arteriosclerosis, atherosclerosis, myocardial infarction, stroke, thrombosis, angina, coronary plaque inflammation, bacterial induced inflammation, viral induced inflammation and inflammation associated with surgical procedures, which comprises treating the subject with a therapeutically effective amount of a cyclooxygenase-2 inhibitor, or a pharmaceutically-acceptable salt thereof in combination with a lipid lowering drug.

The references relied upon by the examiner are:

Talley et al. (Talley) WO 95/15316 June 8, 1999

(Merck) <http://www.merck/mrkshared/mmanual/section2/chapter15/15c.jsp>

#### GROUND OF REJECTION

Claims 13, 15-17, 19-24, 25-31, 40-43, 45-52, 54-62, and 64-68 stand rejected under 35 USC §103(a) as being unpatentable over Talley in view of Merck.

For the following reasons we vacate the pending rejection, and remand the application to the examiner to reconsider the merits of the claimed invention.

#### DISCUSSION

According to the examiner (Answer, page 11), Talley “teach that [(cyclooxygenase-2)] COX-2 inhibitors would be useful for conditions such as vascular disease and myocardias [sic] ischemia and the like....” In addition, the examiner finds (*id.*), Merck “teaches that HMG-C[o]A reductase inhibitors (statins) can lower LDL levels and prevent unstable angina and MI [(myocardial ischemia)] and decrease the need for surgical coronary revascularization.” The examiner recognizes, however, that Talley and Merck differ from appellants’ claimed invention because they do “not explicitly teach that these two agents [should] be given together.” *Id.* To make up for this deficiency, the examiner

relies on the rule of law set forth in In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), finding “it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” See also In re Crockett, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960) (“the idea of combining [two compounds] would flow logically from the teaching of the prior art and therefore that a claim to their joint use is not patentable”).

We remind the examiner, however, that in order to apply the rule of law set forth in Kerkhoven, Crockett, and others in this line of case law, the two compositions set forth in the prior art must be “useful for the very same purpose.” According to appellants (Brief, page 10), “the two cited references do not teach that the separately disclosed compositions are useful for the very same purpose.” As appellants explain (Brief, page 8), Talley teach that COX-2 inhibitors are useful for treating inflammation associated with vascular diseases and myocardial ischemia. In contrast, Merck is relied upon to teach, “HMG-CoA reductase inhibitors (statins) can lower LDL levels and prevent unstable angia and MI and decrease the need for surgical coronary revascularization.” See Answer, page 11; accord Brief, page 9. Accordingly, we agree with appellants (Brief, page 9), “[t]here is simply no teaching connecting the anti-inflammatory activity of the compounds of … [Talley] and the LDL lowering activity of the statins described in … [Merck].” The prior art relied upon by the examiner does not teach that the two compositions are useful for the very same purpose.

Apparently recognizing the deficiency in the rejection of record, the examiner directs attention to page 2 of appellants' specification. According to the examiner (Answer, bridging paragraph, pages 12-13),

[p]age 2, lines 3-9 of the instant specification discloses that the role of inflammation in cardiovascular disease is becoming more understood. Ridker et al. teach a possible role of inflammation in cardiovascular disease and J. Boyle teaches the association of plaque rupture and atherosclerotic inflammation. Further, page 2, last full paragraph recites the COX-2 inhibitors of the instant invention useful for the prevention of inflammation related cardiovascular disorders.

Initially, we note that the examiner appears to rely on a statement of appellants' invention to support his combination of references. The last paragraph, on page 2 of appellants' specification states, "[t]he present invention is directed to the use of inhibitors of cyclooxygenase-2 for the prevention of inflammation related cardiovascular disorders. More specifically, this invention relates to the use of cyclooxygenase-2 inhibitors or derivatives thereof in preventing cardiovascular disease." As appellants point out (Reply Brief, page 2), "[t]he Answer does exactly what the ... case law forbids – it impermissibly refers to applicants' own specification in an effort to support the tendered obviousness rejection." We agree. Any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned from applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392, 1394-1395, 170 USPQ 209, 212 (C.C.P.A. 1971).

At page 2, lines 3-9 of the specification, appellants disclose, "the role of inflammation in cardiovascular diseases is becoming more understood. Ridker ... describes a possible role of inflammation in cardiovascular disease. J. Boyle ... describes the association of plaque rupture and atherosclerotic inflammation."

To begin we find the examiner's reliance on these references in the argument section of the Answer to be improper. In this regard, we remind the examiner "[w]here a reference is relied on to support a rejection, whether or not in a 'minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection." In re Hoch, 428 F.2d 1341, 1342, n.3, 166 USPQ 406, 407, n.3 (CCPA 1970).

In addition, it is unclear why the examiner found it sufficient to rely on appellants' characterization of Ridker<sup>2</sup> and Boyle<sup>3</sup>, instead of critically evaluating the full text of each document. This excerpt of appellants' specification relied upon by the examiner fails to suggest the combination of an anti-inflammatory such as COX-2 with a lipid-lowering drug such as a statin. However, if the examiner had considered Boyle in its entirety, the examiner would have found that Boyle teach (page 93, column 1, endnotes omitted), "[t]he majority of cases of myocardial infarction (MI) and unstable angina are due to rupture of coronary artery plaques." In addition, Boyle teach (page 98, column 1), "superficial inflammation associated with lipid-rich plaques predisposes ... [coronary plaques] to rupture." Thus, as the title of the Boyle article suggests, Boyle teach

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<sup>2</sup> Ridker, et al. (Ridker), "Inflammation, Aspirin, and the Risk of Cardiovascular Disease in Apparently Healthy Men," New England Journal of Medicine, Vol. 336, pp. 973-979 (1997).

<sup>3</sup> Boyle, J.J. (Boyle), "Association of Coronary Plaque Rupture and Atherosclerotic Inflammation," J. Pathology, Vol. 181, pp. 93-99 (1997).

the association of lipid-rich coronary plaque rupture and atherosclerotic inflammation.

We recognize appellants' emphasis that the claimed method is a prophylactic treatment. See e.g., Reply Brief, page 2, "[a]ll of the appealed claims are directed to a method for the prophylactic treatment of a subject at risk of developing a specific set of cardiovascular disorders. The Answer effectively ignores the claimed limitation to prophylactic treatment...." However, Merck teach (first sentence, under the heading "Treatment of Elevated LDL), "[t]he major reason for [lipid lowering] therapy [e.g. statin therapy] is to prevent premature development of atherosclerosis and to lessen the likelihood of CAD [(coronary artery disease)] and MI." In addition, Ridker teach (page 973, column 1, and bridging paragraph, pages 978-979), "that anti-inflammatory agents may have clinical benefits in preventing cardiovascular disease."

For the foregoing reasons, we vacate the rejection of record and remand the application to the examiner for further consideration. However, prior to any further action, we encourage the examiner to take a step back and reconsider the merits of the claimed invention in view of Talley, Merck, Ridker and Boyle, in addition to any other available prior art.

If, after having the opportunity to reconsider the record together with the available prior art, the examiner is of the opinion that a rejection under 35 U.S.C. § 103 is necessary, we suggest the examiner review MPEP § 706.02(j) for a model of how to explain a rejection under this section of the statute. Adherence to this model will of necessity require that the examiner consider the patentability of the

claims in an individual manner and set forth the facts and reasons in support of why individual claims are unpatentable. Note however, that any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED and REMANDED

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William F. Smith )  
Administrative Patent Judge )  
*Donald E. Adams* ) BOARD OF PATENT  
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*Eric Grimes* ) APPEALS AND  
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